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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the OSTEOSET® BVF Kit.

Submitted By:	Wright Medical Technology, Inc.
Date:	February 22, 2001
Contact Person:	Ehab M. Esmail Manager of Regulatory Affairs **Phone:** 901-867-4732 **Fax:** 901-867 4630
Proprietary Name:	**OSTEOSET® BVF Kit**
Common Name:	Bone Void Filler
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The intended use for the OSTEOSET® BVF resultant paste is to be injected, digitally packed into open bone void/gap to cure in-situ; or molded into solid pellets that are gently packed into open bone voids/gap that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste/pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

The OSTEOSET® paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

The OSTEOSET® BVF Kit is provided sterile for single use only.

B. DEVICE DESCRIPTION

OSTEOSET® BVF Kits consist of pre-measured surgical grade calcium sulfate, pre-measured mixing solution, and the tools necessary to mix the components into a paste. These products are provided sterile for single patient use. When mixed according to directions, the OSTEOSET® BVF Kit produces biodegradable,

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radiopaque paste/molded pellets that resorb in approximately 30-60 days, when used according to labeling.

After the powder is hydrated using all of the mixing solution supplied in each kit, the resultant paste can be injected, digitally packed into the bone void to cure in-situ; or molded into solid implants that are gently packed into non-load bearing voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The implants provide a bone void filler that resorbs and is replaced with bone during the healing process.

The paste/beads are used to fill bone voids and may be used at an infected site.

C. MATERIALS

The materials used for the OSTEOSET® BVF Kit are identical to the materials used for previously submitted Wright Plaster of Paris Bone Void Filler:

- The powder supplied in the kit is 98.5% surgical grade calcium sulfate ($CaSO_4 \cdot ½ H_2O$) in conformance with USP/NF Standards for calcium Sulfate, and 1.5% medical grade calcium stearate (stearic acid) in conformance with USP/NF standards for calcium stearate (used as a molding aid). The powder will be supplied premeasured in a glass vial.
- The saline is 0.9% sterile NaCl, USP/NF for irrigation. The saline will be supplied premeasured in a glass vial.

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the OSTEOSET® paste cured in situ are substantially equivalent to the intended use, material composition, and design features of the previously submitted Wright Plaster of Paris Bone Void Filler Kit.

The safety and effectiveness of the OSTEOSET® BVF Kit with the expanded claims is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Mr. Ehab M. Esmail
Manager of Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K010532
Trade/Device Name: OSTEOSET® BVF Kit
Regulatory Class: unclassified
Product Code: MQV
Dated: July 27, 2001
Received: July 30, 2001

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

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OSTEOSET® BVF Kit

INDICATIONS STATEMENT

The intended use for the OSTEOSET® BVF resultant paste is to be injected, digitally packed into open bone void/gap to cure in-situ; or molded into solid pellets that are gently packed into open bone voids/gap that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste/pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

The OSTEOSET® paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

The OSTEOSET® BVF Kit is provided sterile for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ____
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010532